

General

Guideline Title

Radiation management for interventions using fluoroscopic or computed tomographic guidance during pregnancy: a joint guideline of the Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe with Endorsement by the Canadian Interventional Radiology Association.

Bibliographic Source(s)

Dauer LT, Thornton RH, Miller DL, Damilakis J, Dixon RG, Marx MV, Schueler BA, Vañs E, Venkatesan A, Bartal G, Tsetis D, Cardella JF, Society of Interventional Radiology Safety and Health Committee, Cardiovascular and Interventional Radiology Society of Europe Standards of Practice Committee. Radiation management for interventions using fluoroscopic or computed tomographic guidance during pregnancy: a joint guideline of the Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe [trunc]. J Vasc Interv Radiol. 2012 Jan;23(1):19-32. [123 references] [PubMed](#)

Guideline Status

This the current release of the guideline.

Recommendations

Major Recommendations

All persons who perform fluoroscopically or computed tomographic (CT)-guided interventions in pregnant women should be aware of the potential for, and the nature of, radiation adverse effects to patients and the conceptus, as outlined in this guideline. Interventionalists and medical physicists should be knowledgeable of radiation effects and should initiate direct contact with patients and their families, as well as referring physicians, for discussion of these issues.

As in all medical practices involving radiation exposures, interventions should be justified, with the aim of medical exposures doing more good than harm to the patient. Diagnostic and therapeutic modalities that do not use ionizing radiation (e.g., ultrasound [US], magnetic resonance [MR] imaging) should be preferred when clinically appropriate. However, concern about the possible effects of ionizing radiation exposure on the conceptus should not preclude medically indicated diagnostic or interventional x-ray procedures when the medical benefit to the mother is justifiable.

Before fluoroscopically or CT-guided interventions, female patients of childbearing potential should be assessed for the possibility of pregnancy. In cases in which nonurgent high-dose procedure of the abdomen or pelvis (e.g., embolization) is contemplated, the physician should order a pregnancy test.

All facilities should possess, and make available for ready review, references (e.g., those in Tables 4–6 of the original guideline document) that list general radiation dose estimates to the conceptus during radiographic and fluoroscopic imaging. When required, the physician and qualified medical physicist/medical physics expert should estimate radiation dose to the conceptus more accurately, by using scientifically sound methodologies such

as those jointly developed by the Health Physics Society and the American National Standards Institute, or several updated models and methodologies recently developed. The range of uncertainties should also be determined.

All interventions should be optimized to achieve the clinical purposes with no more radiation than is necessary, given the available resources and technology. Optimizing patient or conceptus dose is not the same as minimizing patient or conceptus dose, and it is critically important to achieve the maximum possible dose reduction consistent with acceptable image quality. To that end, appropriate dose reduction techniques, as outlined in Figures 1 and 2 should be employed.

Figure 1: Practical Actions to Control dose to the Pregnant Patient and Conceptus When Performing Image-Guided Fluoroscopic Interventions

- Exclude the conceptus from the direct beam if at all possible.
- Consider arm or neck across instead of groin where appropriate.
- Keep beam-on time to an absolute minimum.
- Consider use of intravascular ultrasound in place of x-ray for portions of the procedure.
- Consider optimal status of the bladder (pre- or post-void) based on the procedure and dose estimates.
- Remember that dose rates will be greater and dose will accumulate faster in larger patients (such as mid- to late-term pregnant patients).
- Keep the tube current as low as possible by keeping the tube potential (kVp) as high as possible to achieve the appropriate compromise between image quality and low patient and conceptus dose.
- Keep the x-ray tube at maximal distance from the patient.
- Keep the image receptor (image intensifier or flat-panel detector) as close to the patient as possible.
- Do not overuse geometric magnification.
- Remove the grid during procedures on small patients or when image intensifier cannot be placed close to the patient.
- Always collimate as tightly as possible to the area of interest.
- When the procedure is unexpectedly prolonged, consider options for positioning the patient or altering the x-ray field or other means to alter direct x-ray field. However, be mindful that such angulations could increase internal x-ray scatter to the conceptus.
- Allow for posterior-anterior beam projections whenever possible.
- Use low-dose-rate pulsed fluoroscopy.
- Use last image hold instead of spot fluorographic images to record the study and to plan technique.
- Minimize exposure from digital subtraction angiography (DSA) by using a low a frame rate as possible by limiting the number of diagnostic/therapeutic goal. It may be possible to substitute fluoroscopic loops for DSA when the higher image quality provided by DSA is not clinically needed.

Figure 2: Practical Actions to Control Dose to the Pregnant Patient and Conceptus when Performing Image-Guided CT Interventions Including Conventional CT Guidance and CT Fluoroscopy

- Exclude the conceptus from the direct beam if at all possible.
- Minimize craniocaudal scanning length and beam width. Note that the scanogram only indicates where the image data are to be acquired and not where the x-ray beam starts and stops.
- Use the quick-check or intermittent acquisition method instead of real-time acquisition during interventional device placement.
- Minimize total exposure time.
- Keep the tube current (mAs) per rotation as low as possible to achieve the appropriate compromise between image quality and low patient and conceptus dose. Consider the use of automatic exposure control modes. The dose is directly proportional to the selected mAs per rotation. Use more recently available novel reconstruction algorithms to reduce noise in images thus allowing reduction of tube current or increase of noise level requirements during scanning.
- Reduce tube voltage (kV) to achieve the appropriate compromise between image quality and low patient and conceptus dose. Decreasing the tube voltage from 140 kV down to 110 kV will decrease the dose by approximately 60% with constant mA.
- Use pitch values greater than 1. Doubling the pitch will reduce the dose by a factor of two.
- Use coarser beam collimation. Fine collimation increases the dose.
- Obtain a single scout view and avoid directly imaging the conceptus for planning purposes.
- Avoid imaging in multiple phases.
- Exclude the conceptus from the direct beam if at all possible.
- Minimize the craniocaudal scanning length and beam width. Note that the scanogram only indicates where the image data is to be acquired and not where the x-ray beam starts and stops.
- Utilize the quick-check or intermittent acquisition method instead of real-time acquisition during interventional device placement.
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- Reduce tube voltage (kV) to achieve the appropriate compromise between image quality and low patient and conceptus dose.

Decreasing the tube voltage from 140 kV down to 110 kV will decrease the dose by about 60% with constant mA.

- Use pitch values greater than 1. Doubling the pitch will reduce the dose by factor of two.
- Use coarser beam collimation. Fine collimation increases the dose.
- Obtain a single scout view and avoid directly imaging the conceptus for planning purposes.
- Avoid imaging in multiple phases.

All equipment should be properly maintained and periodically inspected for radiation safety. Radiation output should be monitored and patient dose recorded according to local regulations and hospital policy.

Pregnant patients should be counseled based on sound information about the risks of radiation exposure. All discussions with patients about radiation risks, as well as the results of any conceptus and/or patient radiation dose assessments or estimates, should be documented in the procedure report and the patient's medical record. Patients should be given the results of these assessments or estimates.

Termination of pregnancy as a result of radiation exposure is an individual decision affected by many factors. An evaluation of overall risks should be undertaken at all dose levels. Conceptus doses lower than 100 mGy should not be considered a reason for terminating a pregnancy. Note that radiographic, fluoroscopic, and CT examinations performed in extraabdominal areas typically deliver doses to the conceptus lower than 1 mGy and that conceptus doses from examinations of the abdomen and pelvis rarely exceed 50 mGy. Estimated doses greater than 100 mGy should initiate an overall review of the potential risks, given the gestational age and patient history.

Pregnant women should not be involved in biomedical research projects involving fluoroscopically or CT-guided interventions (or other radiation exposure) unless the pregnancy itself is central to the research and only if alternative techniques involving less risk cannot be used.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Any disease or condition requiring fluoroscopic or computed tomographic (CT) interventional procedures
- Pregnancy

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Clinical Specialty

Family Practice

Obstetrics and Gynecology

Radiology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Nurses

Physicians

Guideline Objective(s)

- To assist interventionalists and their staff in managing and counseling pregnant patients who need fluoroscopically or computed tomographic (CT)-guided interventional procedures.
- To provide guidance on evaluating possible pregnancy before the interventional procedures and avoiding accidental exposure of conceptus during the first postconception weeks, or performing a necessary urgent procedure under detailed informed consent

Target Population

Pregnant patients who need fluoroscopically or computed tomographic (CT)-guided interventional procedures

Interventions and Practices Considered

1. Assess for possible pregnancy before procedure
2. Obtain radiation dose estimates to the conceptus (e.g., Health Physics Society, American National Standards Institute)
3. Evaluate overall risks and optimize the radiation dose needed to achieve clinical purposes
4. Use properly maintained equipment
5. Counsel pregnant patients, preprocedure and postprocedure
6. Record patient dose data in patient's medical record
7. Follow-up evaluation

Major Outcomes Considered

- Effects of ionizing radiation on the conceptus
- Estimated radiation dose to conceptus

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

An in-depth literature search is performed using electronic medical literature databases. PubMed and Medscape were utilized to perform the literature searches for this guideline.

In order to include the latest literature, the literature was searched from 2000 till present time prior to publication. This was based on the fact that the International Commission on Radiological Protection had published a comprehensive general updated document on Pregnancy and Medical Radiation at that time. Note that significant publications prior to 2000 were also included as primary references.

Only peer-reviewed literature or national/international society or agency-based guidance was utilized. Pregnancy and Medical Radiation, and Pregnancy and Interventional Radiology were primary search terms. Additional references were pulled from those references as applicable to the guide.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

A critical review of peer-reviewed articles and regulatory documents is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is evaluated and used to write the document such that it contains evidence-based data, when available.

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 committee members using a Modified Delphi Consensus Method. Consensus is defined as 80% Delphi participant agreement on a value or parameter. Recommendations are derived from critical evaluation of the literature and evaluation of empirical data from the Safety and Health Committee and the Standards of Practice committee members' practices. Agreement was reached on all statements in this document without the need for modified Delphi consensus techniques.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

The draft document is critically reviewed by the Society of Interventional Radiology (SIR) Safety and Health Committee and separately by the Cardiovascular and Interventional Society of Europe (CIRSE) Standards of Practice Committee by means of telephone, conference calling, or face-to-face meeting. The finalized draft from the Committees is sent to the SIR membership for further input and criticism during a 30-day comment period. These comments are discussed by the SIR Safety and Health Committee and CIRSE Standards of Practice Committee, and appropriate revisions are made to create the finished document. Before its publication, the document is endorsed by the SIR Executive Council and the CIRSE Executive Committee.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate radiation management for interventions using fluoroscopic or computed tomographic guidance during pregnancy

Potential Harms

- It has long been known that the developing conceptus is highly radiosensitive. Exposure of the conceptus to ionizing radiation can potentially lead to two types of adverse health effects, deterministic effects and stochastic effects. Deterministic effects (ie, tissue reactions) result from damage to multiple cells and may be severe enough to cause cell sterilization or death. Stochastic effects originate from damage to single cells that is sufficient to cause a mutation but that does not impair cell division. Stochastic effects (principally cancer) increase in likelihood as dose increases. Two types of risks must be addressed: the likelihood of an adverse outcome and the severity of such an outcome.
- The developing conceptus is radiosensitive throughout the prenatal period. The effects of radiation exposure on the conceptus depend on multiple variables including the gestational age, fetal cellular repair mechanisms, and the absorbed radiation dose level. Higher doses of ionizing radiation can cause embryonic death, congenital malformations, growth retardation, and neurologic detriment. However, there is little support in the epidemiologic literature for the hypothesis that very low doses of radiation adversely affect pregnancy outcome. Much of the current knowledge of the harmful effects of ionizing radiation is from the follow-up of atomic bomb survivors, from patients who received radiation therapy for nonmalignant conditions, and from animal studies. Considerable uncertainty still exists about the risks associated with radiation in the diagnostic dose range. For specific risks concerning the biologic effects of ionizing radiation on the conceptus, central nervous system effects, cardiovascular effects, cancer risks and congenital malformations and growth retardation risks; see the original guideline. Also see Table 1. of the original guideline for deterministic radiation effects at different stages of gestation.

Qualifying Statements

Qualifying Statements

- Much of the current knowledge of the harmful effects of ionizing radiation is from the follow-up of atomic bomb survivors, from patients who received radiation therapy for nonmalignant conditions, and from animal studies. Considerable uncertainty still exists about the risks associated with radiation in the diagnostic dose range.
- The clinical practice guidelines of Society of Interventional Radiology (SIR) attempt to define practice principles that generally should assist

in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

- The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Food and Drug Administration, the Department of Health and Human Services, or the United States Government.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Dauer LT, Thornton RH, Miller DL, Damilakis J, Dixon RG, Marx MV, Schueler BA, Vassiliou E, Venkatesan A, Bartal G, Tsetis D, Cardella JF, Society of Interventional Radiology Safety and Health Committee, Cardiovascular and Interventional Radiology Society of Europe Standards of Practice Committee. Radiation management for interventions using fluoroscopic or computed tomographic guidance during pregnancy: a joint guideline of the Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe [trunc]. J Vasc Interv Radiol. 2012 Jan;23(1):19-32. [123 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Jan

Guideline Developer(s)

Cardiovascular and Interventional Radiological Society of Europe - Nonprofit Organization

Society of Interventional Radiology - Medical Specialty Society

Source(s) of Funding

Society of Interventional Radiology

Guideline Committee

Society of Interventional Radiology Safety and Health Committee

Cardiovascular and Interventional Radiology Society of Europe Standards of Practice Committee

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Financial Disclosures/Conflicts of Interest

Robert G. Dixon, MD is an education consultant for Bard.

None of the other authors have identified a conflict of interest.

Guideline Endorser(s)

Canadian Interventional Radiology Association - Medical Specialty Society

Guideline Status

This the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the [Society of Interventional Radiology Web site](#) .

Print copies: Available from the Society of Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on September 27, 2012. The information was verified by the guideline developer on November 12, 2012.

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